K014171

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

MAR 15 2002

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the ADVANCE® Unicondylar Knee System.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 19, 2001
Contact Person:	Ehab M. Esmail Manager, Regulatory Affairs
Proprietary Name:	ADVANCE® Unicondylar Knee System
Common Name:	UNICONDYLAR KNEE SYSTEM
Classification Name and Reference:	21 CFR 888.3520 Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer – Class II 21 CFR 888.3530 Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer – Class II
Device Product Code and Panel Code:	Orthopedics/87/ HSX, HRY

DEVICE INFORMATION

A. INTENDED USE

Indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

K014171

Unicondylar knee system is indicated for patients with unicompartmental joint disease secondary to the above indications with or without valgus, varus, or flexion deformities where all ligaments are intact.

The ADVANCE® Unicondylar Knee System components are for single use only.

The ADVANCE® Unicondylar Knee System components are for cemented use only.

B. DEVICE DESCRIPTION

The ADVANCE® Unicondylar modular metal-backed tibia is part of the ADVANCE® Unicondylar Knee System that was previously submitted and cleared under 510(k): K012591- ADVANCE® Unicondylar Knee System. Wright Medical Technology is now enhancing the ADVANCE® Unicondylar Knee System by adding a modular titanium metal-backed UHMWPE tibial component. The ADVANCE® Unicondylar Knee System now contains the following components; Co-Cr femoral component, all-poly ultra-high molecular-weight polyethylene (UHMWPE) tibial component and modular titanium metal-backed UHMWPE tibial component.

The ADVANCE® Unicondylar femoral component is identical to the femoral component previously submitted and cleared under ADVANCE® Unicondylar Knee System – 510(k): K012591.

The ADVANCE® Unicondylar all-poly tibial component is identical to the all-poly tibial component previously submitted and cleared under ADVANCE® Unicondylar Knee System – 510(k): K012591.

The ADVANCE® Unicondylar modular metal-backed tibial base is manufactured from titanium (ASTM F136). The ADVANCE® Unicondylar modular tibial insert is manufactured from the identical UHMWPE as the ADVANCE® Unicondylar all-poly tibial components (510(k): K012591). The profile and sizing (Sizes 1, 2, 3 & 4) of the ADVANCE® Unicondylar modular metal-backed tibial components are identical to the ADVANCE® Unicondylar all-poly tibial components (510(k): K012591). The cement interface for the ADVANCE® Unicondylar modular metal-backed tibial components consist of a peripheral dovetail and two pegs and is substantially equivalent to the cement interface of the ADVANCE® Unicondylar all-poly tibial components (510(k): K012591). The articulating surface is identical for both the ADVANCE® Unicondylar modular metal-backed tibial insert and the all-poly tibial component (510(k): K012591). The locking mechanism for the ADVANCE® Unicondylar modular metal-backed tibial components is substantially equivalent to the ADVANTIM® Unicondylar modular metal-backed tibial components (510(k): K881779). Table 1 is a comparison chart summarizing the above design features for the ADVANCE® Unicondylar modular metal-backed tibial components.

K014171

Table 1 - Comparison Between the ADVANCE® Unicondylar Modular Metal-Backed Tibial Components and the ADVANCE® Unicondylar All-Poly Tibial Component

Design Feature	ADVANCE® Unicondylar All-Poly Tibial Component (510(k): K012591)	ADVANCE® Unicondylar Modular Metal-Backed Tibial Components
Material	**All-poly Tibial Component** – UHMWPE (previously submitted and cleared under ADVANCE® Unicondylar Knee System – 510(k): K012591)	**Tibial Insert** - UHMWPE – Insert (Identical to the material used for the ADVANCE® Unicondylar All-Poly Tibial Component - 510(k): K012591 and the ADVANTIM® Unicondylar modular metal-backed tibial base- 510(k): K881779) **Tibial Base** - Titanium (Identical to material used for the ADVANTIM® Unicondylar modular metal-backed tibial base- 510(k): K881779)
Cement Interface	2 pegs with peripheral dovetail (previously submitted and cleared under ADVANCE® Unicondylar Knee System – 510(k): K012591)	2 pegs with peripheral dovetail (substantially equivalent to the ADVANCE® Unicondylar All-Poly Tibial Component - 510(k): K01259)
Articulating Surface	Previously submitted and cleared under ADVANCE® Unicondylar Knee System – 510(k): 012591 -Exhibit 1	Identical to the articulating surface used on the ADVANCE® Unicondylar All-Poly Tibial Component - 510(k): K012591
Profile/Sizing	Previously submitted and cleared under ADVANCE® Unicondylar Knee System – 510(k): 012591 -Exhibit 1	Identical profile and sizing scheme as the ADVANCE® Unicondylar All-Poly Tibial Component - 510(k): K012591
Locking Mechanism	Not Applicable (one piece all-poly tibial component)	Peripheral lock is substantially equivalent to the ADVANTIM® Unicondylar modular metal-backed tibial components (510(k): K881779)

The design features of ADVANCE® Unicondylar modular metal-backed tibial components are substantially equivalent to the design features of the ADVANCE® Unicondylar All-Poly Tibial Component - 510(k): K012591 and the ADVANTIM® Unicondylar modular metal-backed tibial base (Submitted and cleared under 510(k) – K881779 Whiteside Ortholoc II Unicondylar Knee System).

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the ADVANCE® Unicondylar Knee System are substantially equivalent to the ADVANTIM® Unicondylar Femoral component (Submitted and cleared under 510(k) – K881779 Whiteside Ortholoc II Unicondylar Knee System) and also to predicate devices previously cleared for market. The safety and effectiveness of the ADVANCE® Unicondylar Knee System are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2002

Mr. Ehab M. Esmail
Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K014171
Trade/Device Name: ADVANCE® Unicondylar Knee System
Regulation Number: 21 CFR 888.3530 and 888.3520
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis and knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY and HSX
Dated: December 19, 2001
Received: December 20, 2001

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014171

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

ADVANCE® Unicondylar Knee System

INDICATIONS STATEMENT

Indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

Unicondylar knee system is indicated for patients with unicompartmental joint disease secondary to the above indications with or without valgus, varus, or flexion deformities where all ligaments are intact.

The ADVANCE® Unicondylar Knee System components are for single use only.

The ADVANCE® Unicondylar Knee System components are for cemented use only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014171

Prescription Use ____
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company